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1 2 alleging that Defendant Becton Dickinson & Company ("Becton Dickinson") infringes its Automation<sup>1</sup> 3 4 5 6 7 8 9 10 11 12 13

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and Cap Patents.<sup>2</sup> One motion to dismiss and five motions for summary judgment are before the Court:<sup>3</sup> (1) Becton Dickinson's Motion to Dismiss for Lack of Subject-Matter Jurisdiction; (2) Becton Dickinson's Motion for Summary Judgment of Invalidity of the '308 Patent; (3) Becton Dickinson's Motion for Summary Judgment of Invalidity of the Automation Patents; (4) Gen-Probe's Motion for Summary Judgment of Infringement of the '308 Patent; (5) Gen-Probe's Motion for Partial Summary Judgment of Infringement and No Invalidity of the Automation Patents; and (6) Becton Dickinson's Motion for Summary Judgment of Non-Infringement of the Automation Patents. The motions have been fully briefed and the Court heard oral argument on June 21, 2012, August 30, 2012, and September 12, 2012. The Court rules as follows.

This is a patent infringement action brought by Plaintiff Gen-Probe Incorporated ("Gen-Probe")

### **BACKGROUND**

The Automation Patents at issue in this action result from Gen-Probe's development of a single automated instrument to detect a target nucleic acid indicative of the presence of a target pathogen within a sample. The Cap Patents describe a specimen collection vessel that allows the contents of the vessel to be sampled by an automated device.

In this action, Gen-Probe accuses Becton Dickinson of infringing claims of the Automation Patents and Cap Patents through the use and sale of the VIPER XTR and BD Max, Becton Dickinson's automated nucleic acid test instruments, and numerous penetrable cap products.

The Automation Patents describe an automated method of nucleic acid-based testing where the automated analyzer detects the presence of a particular pathogen in a sample. Nucleic acid-based testing involves the creation of a complementary nucleotide sequence that a target pathogen will bind to through complementary base pairing. The complementary nucleotide sequence is used as a probe.

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<sup>&</sup>lt;sup>1</sup>U.S. Patent Nos. 7,118,892 (the '892 Patent), 7,560,255 (the '255 Patent), 7,482,143 (the '143 Patent), and 7,542,652 (the '652 Patent).

<sup>&</sup>lt;sup>2</sup>U.S. Patent Nos. 6,893,612 (the '612 Patent) and 7,294,308 (the '308 Patent).

<sup>&</sup>lt;sup>3</sup>Gen-Probe recently filed a Motion to Strike Becton Dickinson's First Amended Answers and Counterclaims, but the parties have not completed briefing on the Motion. The Motion is set for hearing on October 9, 2012.

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The probe is introduced to a sample that may contain the target nucleic acid. If the target binds to the probe, it indicates that the target nucleic acid is present in the sample. The Automation Patents automate the steps of this process in a single instrument. The Cap Patents use a seal or seals on a collection vessel that are penetrated by a fluid transfer device. The seal or seals, in conjunction with the core structure, are intended to prevent the release of aerosols from the sample and limit contamination from fluid on the fluid transfer device after removal.

### **DISCUSSION**

"Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. However, summary judgment should be granted only when no reasonable jury could return a verdict for the nonmoving party. In determining whether there is a genuine issue of material fact in dispute, the evidence must be viewed in the light most favorable to the nonmoving party, and all reasonable inferences must also be drawn in favor of the nonmovant." Fin Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1317 (Fed. Cir. 2001) (internal citations and quotations omitted).

#### I. Motion to Dismiss for Lack of Subject-Matter Jurisdiction

Becton Dickinson moves to dismiss Gen-Probe's claims for infringement of the Automation Patents. Becton Dickinson claims Gen-Probe lacks standing to assert infringement because it does not possess complete ownership of the Automation Patents. Becton Dickinson asserts that Mark Toukan is an omitted inventor of the Automation Patents based on his work on a luminometer and Gen-Probe has not obtained assignment of his ownership rights.

Gen-Probe hired RELA to design an instrument that would automate Gen-Probe's nucleic acid testing. Toukan worked on the luminometer module of the instrument for RELA as an independent contractor from October 1996 to October 1997. The luminometer is the detection step of the automated process. RELA assigned all its rights in the invention to Gen-Probe.<sup>4</sup>

Becton Dickinson has produced evidence that Toukan contributed to the development of a prototype of the luminometer described in the May 1998 provisional application of the Automation Patents. The May 1998 provisional application contains a common specification that includes

<sup>&</sup>lt;sup>4</sup>The parties do not dispute that RELA assigned its rights to Gen-Probe.

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drawings of the luminometer that are almost identical to Toukan's drawings of his prototype. Additionally, Becton Dickinson has produced evidence that Toukan was the engineer responsible for the luminometer design while at RELA and passed his work on to Ralph Burns when he left the project. Becton Dickinson has also produced evidence that Gen-Probe sought an assignment of Toukan's potential ownership rights based on his work on the luminometer.

Gen-Probe has produced evidence that many of the components of Toukan's prototype were designed by other engineers before Toukan started work on the project, Toukan's design did not work, particularly within an integrated instrument, and that Burns redesigned the luminometer through significant trial and error and experimentation to resolve problems with Toukan's design.

"Patent issuance creates a presumption that the named inventors are the true and only inventors." Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). Becton Dickinson conceded at the August 30, 2012 hearing that it bears the burden of proving Toukan's inventorship. Inventorship must be proven by clear and convincing evidence. *Id.* Becton Dickinson has not carried its burden.

Becton Dickinson argues there are no material disputes of fact concerning inventorship and the Court should find that Toukan is an inventor as a matter of law. But, "[i]nventorship is a mixed question of law and fact: The overall inventorship determination is a question of law, but it is premised on an underlying question of fact." Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1362 (Fed. Cir. 2004); see also Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997) ("The determination of whether a person is a joint inventor is fact specific"). As explained below, the facts underlying the inventorship determination are disputed. Because the subject-matter jurisdiction determination turns on disputed issues of fact, the Court applies the standards for summary judgment.<sup>5</sup> Trentacosta v. Frontier Pac. Aircraft Indus., Inc., 813 F.2d 1553, 1558 (9th Cir. 1987).

<sup>&</sup>lt;sup>5</sup>Becton Dickinson and Gen-Probe agreed at the August 30, 2012 hearing that the Court should analyze this motion under a summary judgment standard.

<sup>6&</sup>quot;A dismissal for lack of subject matter jurisdiction is a procedural question not unique to patent law, therefore, [the Court] follow[s] the law of the regional circuit." Madey v. Duke Univ., 307 F.3d 1351, 1358 (Fed. Cir. 2002).

There are disputed issues of fact concerning when conception occurred. "Conception is the touchstone of inventorship, . . . the formation in the mind of the inventor of a definite and permanent idea of the *complete and operative invention*, as it is hereafter to be applied in practice." *Burroughs Wellcome Co v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994) (emphasis added). While reduction to practice is not required, "[c]onception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or *experimentation*." *Id.* at 1228 (emphasis added). Becton Dickinson has produced evidence of Toukan's contributions to the luminometer, including the drawings of his design that appear in the specification, but Gen-Probe has produced evidence that Burns engaged in significant trial and error experimentation to arrive at the design that was operative and that Toukan admitted that his luminometer prototype was not complete when he passed his work on to Burns.

Additionally, there are disputed issues of fact concerning the quality of Toukan's contribution in light of the work of prior engineers. "[T]o be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." *Fina*, 123 F.3d at 1473. The Toukan drawings in conjunction with Toukan's time on the project suggest his contribution to the analyzer could be considered "not insignificant," but Gen-Probe's evidence that most of the components Toukan relied on in his work came from prior engineers and evidence that Burns made significant changes to the luminometer to make it operational as part of the analyzer suggest otherwise. Whether Toukan's contribution was not insignificant in quality depends on disputed issues of fact.

Because there are disputed issue of fact concerning Toukan's inventorship, the Court **DENIES**Becton Dickinson's Motion to Dismiss for Lack of Subject Matter Jurisdiction.

## II. Invalidity

# A. Written Description Requirement<sup>7</sup>

 $Becton\,Dickins on\,moves\,for\,summary\,judgment\,of\,invalidity\,of\,the\,asserted\,claims\,of\,the\,'308$ 

<sup>&</sup>lt;sup>7</sup>Gen-Probe also seeks summary judgment of no invalidity on the written description requirement based on alleged deficiencies in Becton Dickinson's expert report.

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8'308 Patent, claims 1, 4, 17, 18, 20, and 21.

Dickinson also moves for summary judgment of invalidity of the asserted claims of the Automation Patents arguing that the specification only describes the performance of an automated assay in a single, open reaction receptacle moved from one location to another using a transport mechanism. 

"Compliance with the written description requirement is a question of fact, but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving

Patent arguing the specification lacks a description of a penetrable cap without a filter.<sup>8</sup> Becton

summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008). The written description requirement ensures that the claims do "not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The description does not need to track the asserted claims verbatim, it need only "indicate to a person skilled in the art that the inventor was 'in possession' of the invention as later claimed." *PowerOasis*, 522 F.3d at 1306 (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

"To overcome the presumption of validity of patents, the accused must show that the claims lack a written description by clear and convincing evidence." *Hynix Semiconductor, Inc. v. Rambus, Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Because these motions are before the Court on summary judgment, to prevail, Becton Dickinson "must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). The Court must draw all reasonable inferences in favor of Gen-Probe, the non-moving party. *Id.* 

<sup>&</sup>lt;sup>9</sup>'892 Patent, claims 4, 11, and 28; '143 Patent, claims 1, 5, 7, 11, 17, and 18; '652 Patent, claims 1, 2, 7, 9, 14, and 15; '255 Patent, claims 1, 3, 6, 13, and 16.

### 1. '308 Patent

Becton Dickinson argues that the '308 Patent specification fails to convey that the inventors invented a penetrable cap *without* a filter because the specification only describes a cap *with* a filter. Relying on the specification itself, Becton Dickinson accurately notes that there are no figures lacking a filter, that the invention is primarily described with a filter, including within the Abstract and introductory paragraph of the Summary of the Invention section.

Gen-Probe does not dispute that the specification primarily describes a cap with a filter, but Gen-Probe characterizes the description with a filter as a preferred embodiment. Gen-Probe argues that the specification contains a description without a filter and that a person of skill in the art would understand that the specification includes a cap without a filter.

Within the Summary of the Invention section, the specification outlines a series of different embodiments of the cap including the embodiment Gen-Probe relies on:

In still another embodiment, a method is provided for removing a fluid substance contained in a closed system comprising a cap and a fluid-holding vessel. In addition to the cap and vessel components, the phrase "closed system" is used herein to refer to a cap that is fixed to a vessel in sealing engagement to prevent the fluid contents of the system from escaping into the surrounding environment. The method includes penetrating first and second frangible seals affixed to the cap with a fluid transfer device, where the second seal is axially aligned below the first seal. Penetration of the first and second seals by the fluid transfer device results in the formation of air passageways between the seals and the fluid transfer device which aid in venting air from the interior space of the system. The fluid transfer device is preferably a plastic pipette tip for use with an air displacement pipette. In a *preferred mode*, the method *further includes* passing the fluid transfer device through *a filter* contained within the cap and interposed between the first and second seals.

('308 Patent at 5:33-36 (emphasis added).) Gen-Probe argues that this language discloses an embodiment with two frangible seals and no filter that is modified "in a preferred mode" to "further include" a filter. Becton Dickinson argues that the preferred mode described is not the addition of the filter to a filterless cap, but rather the placement of the filter between the two seals.

Becton Dickinson emphasizes the first paragraph of the Summary of the Invention section which lists six components of the invention, including "filtering means" to prevent contamination ('308 Patent at 3:25-45.) Becton Dickinson characterizes these as necessary key elements of the invention, but as Gen-Probe notes, the embodiment lacking a filter is also in the Summary of the Invention section. Additionally, the entire Summary of the Invention section is a series of paragraphs

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that describe various embodiments of the invention that vary from the elements in this introductory paragraph, including the one above.

Unlike the cases Becton Dickinson relies on, here there is a disclosure in the specification that can be interpreted as describing a cap without a filter. *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376, 1379 (Fed. Cir. 2009) ("ICU has failed to point to any disclosure in the patent specification that describes a spikeless valve with a preslit trampoline seal."); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (finding description of one method to achieve an objective insufficient to support all means for achieving that objective).

While the Court must view the specification as a whole, the Court cannot ignore this disclosure of an embodiment that can fairly be interpreted as a cap lacking a filter, particularly when the Court must draw all reasonable inferences in Gen-Probe's favor. *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, — F.3d —, 2012 WL 3329695, at \*13 (Fed. Cir. 2012) ("Because factual inferences must be drawn in favor of the nonmoving party on summary judgment, we find that the district court's decision cannot stand."). The description of a "preferred mode" that "further includes" a filter suggests the preceding description of the cap is a non-preferred mode that does not include a filter. In light of this language in the specification, the Court cannot find that Becton Dickinson has met it burden to provide "such clear and convincing evidence of invalidity that no reasonable jury could find otherwise." *Eli Lilly*, 251 F.3d at 962. Accordingly, the Court **DENIES** Becton Dickinson's Motion for Summary Judgment of Invalidity of the '308 Patent claims based on the written description requirement.

## 2. Automation Patents

Becton Dickinson argues that the common specification only discloses an automated analyzer that moves an open reaction receptacle in which all reactions occur, using a transport mechanism, through a series of stations with amplification and detection taking place sequentially. But, Becton Dickinson argues, the asserted claims of the Automation Patents expand beyond this disclosure because the asserted claims do not require completion of all the assay steps in a single reaction receptacle, do not require the use of a transport mechanism, and cover amplification and detection taking place in the same receptacle simultaneously. Becton Dickinson also provides expert testimony that the specification would convey to a person of skill in the art that the inventors possessed only the

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specific embodiment outlined in the specification. (van Gemen Decl. ¶¶ 19, 29.)

Gen-Probe argues that summary judgment is not appropriate because Becton Dickinson has not met its burden to provide clear and convincing evidence that each claim lacks the necessary disclosure in the specification and there are factual disputes regarding what the specification discloses to a person of ordinary skill in the art. Gen-Probe also emphasizes that the specification is not as limited as Becton Dickinson portrays it because the specification discusses numerous amplification techniques and references their use with modification, describes moving samples using a robotic pipettor, tubes, nozzles, and delivery lines, and "closing" the receptacle with an oil overlay. Gen-Probe also provides expert testimony that a person of skill in the art reading the specification would understand the inventors possessed the full scope of the claims. (Kricka Decl. ¶ 25.)

The common specification describes the movement of reaction receptacles, in which all reactions take place, from station to station using a transport mechanism. Unlike the '308 Patent previously discussed, the common specification of the Automation Patents does not contain a disclosure of a non-preferred embodiment or example in which a sample is transferred out of the reaction receptacle, the reaction receptacle is closed, the reaction receptacle is moved by means other than a transport mechanism, or amplification is done simultaneously. If Gen-Probe were required to specifically describe or provide an example in the specification of the analyzer performing these functions in this way, the Court could grant summary judgment to Becton Dickinson. But, that is not the law. *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009) (summarizing cases and finding "[a] patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed."); *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (finding examples unnecessary to satisfy written description requirement).

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<sup>&</sup>lt;sup>10</sup>Gen-Probe also argues that its general language in the specification that "the invention is not to be limited to the disclosed embodiments, but, on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims" allows it to encompass the asserted claims that were added at a later date. Gen-Probe has not cited any cases in which courts have relied on this boilerplate language and reliance on the language would seem to undercut the written description requirement. However, the Court need not reach this issue because disputed issues of fact preclude summary judgment.

Rather, the Court must evaluate what the specification "reasonably conveys to those skilled in

(Fed. Cir. 2011). This inquiry raises disputed issues of fact. The parties' respective experts provide

conflicting testimony on whether one of skill in the art reading the specification would understand the

1 2 the art." Ariad, 598 F.3d at 1351; Boston Scientific Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366 3 4 5 inventors possessed the full scope of the asserted claims. 11 Becton Dickinson's expert, Dr. van 6 Gemen, reviews and summarizes the embodiment described in the specification and concludes "that 7 a person of ordinary skill in the art reading the common specification . . . would not understand that 8 the inventors possessed all of the approaches to automation that are encompassed within the broad 9 claims asserted." (van Gemen Decl. ¶ 29.) Dr. Kricka, Gen-Probe's expert, concludes the opposite. 10 Dr. Kricka identifies numerous specific common features disclosed in the specification and explains how these features combined with the knowledge of a person skilled in the art would convey that the 11 12 inventors possessed the full scope of the asserted claims. (Kricka Decl. ¶¶ 17, 19-24.) Additionally, he explains point-by-point why he disagrees with Dr. van Gemen's opinions by identifying specific 13 14 disclosures in the specification that contradict Dr. van Gemen's conclusions. Faced with these 15 disputed facts, the Court must deny summary judgment. SunTiger, Inc. v. Scientific Research Funding 16 17 18 specification disclosed).

В.

### Anticipation

Becton Dickinson moves the Court for summary judgment that the claims of the '308 Patent are anticipated by three prior art references: Penetrable Cap and Fluid Transfer Device for Use Therewith ("Anderson"); "Pierceable Stopper and Method of Producing the Same ("Naritomi"); and Plug Body for a Container ("Maruyama"). Gen-Probe moves for summary judgment of no anticipation on two prior art references identified by Becton Dickinson as anticipating '143 Patent claims — the "Collins '829" and "Tajima '739" references.

Grp., 189 F.3d 1327, 1334 (Fed. Cir. 1999) (affirming denial of summary judgment based on "an old

fashioned factual dispute" when parties presented conflicting affidavits addressing what the

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<sup>&</sup>lt;sup>11</sup>Both parties accuse the other's expert of being conclusory. However, both experts provide detailed explanations for their opinions relying on the specification and their knowledge of what a person of skill in the art would know.

must be clear and convincing. *Schumer v. Lab. Computer Sys.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002). "The burden of proving invalidity on summary judgment is high." *Id.* at 1316. It is well settled that a claim is anticipated if each and every limitation [of the claim] is found either expressly or inherently in a single prior art reference." *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

## 1. '308 Patent

The '308 Patent only has one independent claim, Claim 1. Therefore, if Becton Dickinson fails to meet its burden on Claim 1, it fails to meet its burden on the claims that depend on Claim 1. Because the Court finds Becton Dickinson has not met this burden for any of the three references, the Court **DENIES** summary judgment of invalidity for anticipation.

Issued patents enjoy a presumption of validity, and therefore the evidence showing invalidity

### a. Anderson

Anderson discloses a cap that allows ventilation of air when fluid is transferred from the vessel attached to that cap. (Anderson at 4.) It was considered by the Patent and Trademark Office during prosecution of the '308 Patent. The clear and convincing burden of proof associated with the presumption of validity for issued patents becomes "particularly heavy" when a Patent and Trademark Office examiner considered the asserted prior art. *Impax Labs.*, *Inc.* v. *Aventis Pharms*. *Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008).

Figure 5 of Anderson shows a cap with one seal at the top of it. Figure 9 of Anderson shows the same cap of Figure 5 without the seal, but additionally with an "overcap" on top of the cap, and a seal present on top of the "overcap." Becton Dickinson argues that in the embodiment of Anderson that includes a cap and an overcap, there are two frangible seals present. The figures do not depict two seals and the specification describes the cap "generally without a seal," with the overcap. Becton Dickinson argues that "generally" implies that there are situations where the seal is on the cap in addition to the seal on the overcap which results in two seals.

Gen-Probe notes that further in the same paragraph, Anderson states that when there is a seal in the cap and overcap embodiment, the seal is "preferably applied" to the top of the overcap. (Anderson at 21:30.) From this, Gen-Probe argues that Anderson contemplates the presence of only

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one seal, located either between the cap and overcap or on top of the overcap, but not both.

It is not clear from the specification or the figures whether Anderson contemplates an embodiment that contains two seals. Therefore, Becton Dickinson has not shown invalidity by clear and convincing evidence.

### b. Naritomi

Naritomi discloses a "pierceable stopper used for a liquid container into which a hollow needle can be externally inserted through the pierceable stopper," and also a "method of producing the pierceable stopper." (Naritomi at ¶ 1.)

Naritomi seems to show an embodiment with two frangible seals, but Gen-Probe contends that one of the two seals in Naritomi is not affixed to the core structure, and therefore, the limitation of Claim 1 that requires both of the frangible seals to be affixed to the core structure is not met. To this, Becton Dickinson responds by contending that the specification of Naritomi states that the "pierceable stopper comprises a stopper body, a pierceable part, an external hermetic sealing film, and an internal hermetic sealing film," therefore the internal sealing film must be "affixed" to the stopper. It is unclear if Nartitomi's inclusion of the internal sealing film in the list of elements of the pierceable stopper necessarily means that the elements are affixed to each other. Becton Dickinson has not shown invalidity by clear and convincing evidence.

## c. Maruyama

Maruyama discloses a plug for a container where the plug body does not allow foreign matter to enter the container. The plug of Maruyama has two thermoplastic films covering both sides of the rubber plug. (Maruyama at 2: 3-5.) Gen-Probe contends that because the two films in Maruyama are covering the plug, they are not "spaced-apart" as required by Claim 1 of the '308 Patent and consequently, the entire plug, including both film layers, is one "seal". Further, Gen-Probe contends that the seals are not frangible because the plug of Maruyama is not frangible, and since the seals are part of the plug, they are not frangible either.

Becton Dickinson has not met its burden in showing that the two film layers of Maryuama are frangible seals in a way that anticipates Claim 1 of the '308 Patent. Therefore, Becton Dickinson has not shown invalidity by clear and convincing evidence.

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Accordingly, the Court **DENIES** Becton Dickinson's Motion for Summary Judgment of Invalidity of the '308 Patent claims based on anticipation.

## 2. '143 Patent<sup>12</sup>

Gen-Probe argues that it is entitled to partial summary judgment of no anticipation with respect to two prior art references that Becton Dickinson alleges anticipate the '143 Patent claims.

As to Collins '829, Becton Dickinson does not contend that it anticipates '143 Patent claims 1, 5, 11, and 18. Becton Dickinson only argues that the Court should not grant summary judgment on a piecemeal basis for specific prior art and that any decision would be advisory because Becton Dickinson no longer asserts that Collins anticipates these claims. When a moving party points to the "absence of evidence to support the non-moving party's case, with respect to an issue on which the non-movant bears the burden" and the non-movant produces no evidence, the Court should grant summary judgment to the moving party. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1389 (Fed. Cir. 1992) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)). Gen-Probe has pointed to the absence of evidence to support an anticipation defense with respect to the Collins reference and Becton Dickinson has not put forth any evidence. The Court **GRANTS** summary judgment for Gen-Probe of no anticipation of claims 1, 5, 11, and 18 of the '143 Patent with respect to the Collins reference.

As to the Tajima reference, Becton Dickinson has put forth evidence — testimony from its expert — that the Tajima platform provides stations suitable for automated detection and one of ordinary skill would understand Tajima to disclose the integration of the necessary detection components into this platform. This expert testimony is sufficient to raise a triable issue of fact. The Court **DENIES** summary judgment with regard to the Tajima reference.

# C. No Invalidity of Automation Patents

Gen-Probe moves for summary judgment of no invalidity based on deficiencies in Becton Dickinson's experts' reports. Gen-Probe claims that Becton Dickinson's experts failed to provide claim-by-claim analysis of anticipation, obviousness, and written description. Gen-Probe also moves for summary judgment of no invalidity under the enablement requirement.

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<sup>&</sup>lt;sup>12</sup>'143 Patent, claims 5, 11, 17, and 18.

Gen-Probe, as the party "seeking to have a patent held not invalid at summary judgment must show that [Becton Dickinson] . . . failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent." *Id.* The Court must draw all reasonable inferences in favor of Becton Dickinson, the non-moving party. *Id.* 

## 1. Sufficiency of Expert Reports

Gen-Probe asserts that the Court must grant summary judgment on Becton Dickinson's invalidity defenses because Becton Dickinson's experts did not provide analysis of each defense on a claim-by-claim basis. Becton Dickinson argues in opposition that its expert reports are appropriately organized on a claim element-by-claim element basis for efficiency and sufficiently disclose the expert's opinions on anticipation, obviousness, and written description.

Gen-Probe has not cited any authority dictating claim-by-claim analysis in an expert report. Rather, the cases Gen-Probe relies on explain the court's process of first construing the meaning and scope of each claim through construction and then considering each claim as construed. *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 (Fed. Cir. 2004). Additionally, as Becton Dickinson explains in opposition, analysis by claim element may be acceptable and appropriate. *Schumer*, 308 F.3d at 1315 ("Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element," interpret the element and explain the element's disclosure in the prior art).

The Court does not find the substance of the report so deficient that Becton Dickinson has failed to raise a genuine issue of material fact on these defenses and the Court will not grant summary judgment to Gen-Probe on all of Becton Dickinson' invalidity defenses based on the form of Becton Dickinson's expert reports in the absence of any authority requiring an expert report be prepared in a particular way. Accordingly, Gen-Probe's motion for summary judgment of no invalidity on anticipation, obviousness, and written description is **DENIED**.

## 2. Enablement

Gen-Probe seeks summary judgment of no invalidity under the enablement requirement of all the Automation Patents. As with the Collins reference discussed above, Becton Dickinson only argues that the Court should not grant summary judgment because Becton Dickinson is no longer pursuing

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this defense. However, Gen-Probe accurately notes that Becton Dickinson's recently filed amended 1 2 counterclaims assert invalidity under 35 U.S.C. § 112 without distinguishing between written 3 4 5 6 7 8 9

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description and enablement. Additionally, as previously explained, when a moving party points to the "absence of evidence to support the non-moving party's case, with respect to an issue on which the non-movant bears the burden" and the non-movant produces no evidence, the Court should grant summary judgment to the moving party. *Intellicall*, 952 F.2d at 1389 (relying on *Celotex*, 477 U.S. at 325). Gen-Probe has pointed to the absence of evidence to support an enablement defense with respect to the Automation Patents and Becton Dickinson has not put forth any evidence in response. The Court **GRANTS** summary judgment of no invalidity for lack of enablement on the Automation Patents based on Becton Dickinson's failure to produce any evidence on the issue.

#### III. **Non-Infringement**

#### **Automation Patents** A.

Becton Dickinson moves for summary judgment of non-infringement of claim 6 of the '255 Patent ("reaction receptacle") and claims 4, 11, and 28 of the '892 Patent ("provided thereto") based on the doctrine of equivalents.

"The doctrine of equivalents prevents an accused infringer from avoiding infringement by changing only minor or insubstantial details of a claimed invention while retaining their essential functionality." Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1424 (Fed. Cir. 1997). Under the doctrine, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Carnegie Mellon Univ. v. Hoffman-LaRoche, Inc., 541 F.3d 1115, 1129 (Fed. Cir. 2008) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997)).

But, the doctrine's application is not boundless. The doctrine cannot vitiate a claim limitation. *Id.* ("The 'all limitations rule' restricts the doctrine of equivalents by preventing its application when doing so would vitiate a claim limitation."). In determining whether a finding of infringement under the doctrine of equivalents would vitiate a claim limitation, the Court must consider "the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly

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pertinent limitation meaningless." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005). Summary judgment is appropriate under the doctrine when the Court can find that no reasonable jury could find that "the differences between the allegedly infringing devices and the claimed inventions were plainly not insubstantial." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1318 (Fed. Cir. 1998).

characterized as an insubstantial change from the claimed subject matter without rendering the

## 1. "reaction receptacle"

The Court construed "reaction receptacle" as "a vessel in which each reaction of the diagnostic assay is performed." Under this construction, all steps of the assay occur in a single receptacle. Gen-Probe does not dispute that Becton Dickinson's accused products use multiple receptacles, three and five, to perform its nucleic acid assays. However, Gen-Probe argues that performing all assay reactions in a single vessel is not substantially different from performing all reactions in three or five vessels.

To adopt Gen-Probe's position, the Court would have to find that a single vessel and multiple vessels are equivalent. This would render claim 6's requirement for a single vessel in which all reactions of the assay are performed meaningless and essentially read the single vessel limitation, the only limitation imposed by claim 6, out of the claim. *See Carnegie Mellon*, 541 F.3d at 1129 (affirming summary judgment of non-infringement under doctrine). Accordingly, the Court **GRANTS** summary judgment of non-infringement of claim 6 of the '255 Patent.

## 2. "provided thereto"

The Court construed the phrase "provided thereto" in the '892 Patent to require that amplification reagents are "added to the receptacle in which the target nucleic acid was already present." Becton Dickinson's Viper XTR does not add reagents into a receptacle in which the sample is already present. Rather, it pipettes the sample into a microwell that already contains dried reagents. Gen-Probe argues that adding reagents to a receptacle containing the target nucleic acid and adding a target nucleic acid to a receptacle that already contains the reagents is equivalent. This would essentially turn "provided thereto" into "combining."

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Prosecution history estoppel prevents a patentee from relying on the doctrine of equivalents to encompass subject matter surrendered during prosecution because the amendment acknowledges "the difference between the two phrases," making the difference disclaimed material. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002). Gen-Probe does not dispute that the patent examiner required an amendment adding "provided thereto" and that the claims previously only required combining the sample and amplification reagents.

Gen-Probe argues that the amendment was not made for purposes of patentability, as required for prosecution history estoppel to apply. *Id.* at 736. However, the burden is on the patentee, Gen-Probe, to show that an amendment was not for purposes of patentability. *Id.* at 739. "Where no explanation is established . . . the court should presume that the patent application had a substantial reason related to patentability for including the limited element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents." *Id.* at 739-40 (quoting *Warner-Jenkinson*, 520 U.S. at 33). Here, because Gen-Probe has not provided any explanation for the amendment, the Court must presume it related to patentability. Accordingly, prosecution history estoppel bars the application of the doctrine. The Court **GRANTS** summary judgment of non-infringement of claims 4, 11, and 28 of the '892 Patent.

## 3. '612 Patent

Becton Dickinson also moves for summary judgment of non-infringement of claims 1, 7, 18, and 22 of the '612 Patent ("filter") based on the difference between the filter described in the '612 Patent and the "leaves" of its cap.

The Court construed the term "filter" in accordance with the explicit definition provided in the specification:

a material which (1) performs a wiping function to remove fluids present on the outside of a fluid transfer device and/or absoring function to hold or otherwise sequester fluids removed from the outside of a fluid transfer device and (2) has pores or interstices which admit the passage of gas.

Becton Dickinson's cap indisputably includes four molded triangular-shaped hard plastic leaves that extend inward from the side wall of the cap. Gen-Probe does not dispute that the hard plastic leaves do not contain any pores or interstices that admit the passage of gas. Gen-Probe argues

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that the material that makes up the filter does not have to have pores or interstices, but rather "material" refers to the whole of the elements of the filter, *i.e.*, the four hard plastic leaves collectively have interstices which admit the passage of gas. Gen-Probe compares the four hard plastic leaves, that themselves do not have pores or interstices, to the individual acrylic fibers that make up the pile fabric described in the specification as a preferred filter material. However, the preferred filter material is not individual acrylic threads; it is a pile fabric. The fabric has pores or interstices which admit the passage of gas. The hard plastic leaves do not. Accordingly, the Court **GRANTS** summary judgment of non-infringement of claims 1, 7, 18, and 22 of the '612 Patent.

# IV. Infringement

## A. '308 Patent

Gen-Probe seeks summary judgment that Becton Dickinson is infringing Claims 1, 4, and 17 of the '308 Patent. Becton Dickinson concedes that its cap products literally infringe claims 1, 4, and 17 of the '308 Patent as construed by the Court in its claim construction order. The parties' only dispute is whether Gen-Probe is entitled to summary judgment of infringement when Becton Dickinson's invalidity defenses remain to be resolved at trial. Becton Dickinson argues that the Court should not determine infringement until Becton Dickinson's invalidity defenses are resolved. Gen-Probe argues it is entitled to summary judgment of infringement because infringement and invalidity are separate questions.

The Federal Circuit "has long recognized that patent infringement and invalidity are separate and distinct issues." *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). "Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity." *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir.1983). Accordingly, the Court finds Becton Dickinson is infringing claims 1, 4, and 17 of the '308 Patent based on Becton Dickinson's concession and **GRANTS** Gen-Probe's motion for summary judgment.<sup>13</sup>

<sup>&</sup>lt;sup>13</sup>The Court notes that its decision does not constitute a final judgment because "[i]f a case is not fully adjudicated as to all claims for all parties, there is no final decision." *Pandrol*, 320 F.3d at 1321 (internal quotations marks omitted).

### **B.** Automation Patents

Gen-Probe moves for summary judgment of direct literal infringement, inducement of infringement, and contributory infringement of sixteen Automation Patent claims. <sup>14</sup> Because "liability for active inducement of infringement or . . . contributory infringement is dependent upon the existence of direct infringement" the Court first considers whether Gen-Probe is entitled to summary judgment of direct infringement. *RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1268 (Fed. Cir. 2003).

## 1. Direct Infringement

"To infringe a method claim, a person must have practiced all steps of the claimed method." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009). "[A] finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Id.* Becton Dickinson asserts two arguments in opposing Gen-Probe's motion for summary judgment of infringement: (1) Becton Dickinson's amplification product is not the "same as or complementary to a sequence of the target nucleic acid" as required by the asserted claims; and (2) Gen-Probe's expert's testimony on invalidity raises a genuine issue of material fact regarding infringement. The Court finds neither argument persuasive.

### a. Amplification Product

The relevant claim language states, "amplification product . . . wherein the amplification product is a nucleic acid sequence that is the same as or complementary to a sequence of the target nucleic acid." Becton Dickinson interprets this language to mean that the amplification product can only be the target nucleic acid sequence and nothing else. Gen-Probe argues that it only requires that the amplification product contain the target nucleic sequence. The difference is important because Becton Dickinson's amplification product contains both a target nucleic acid sequence and sequences that are not the target nucleic acid. If the amplification product in the asserted claims is limited to the use of an amplification product that contains only the target nucleic acid sequence, then Becton

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<sup>&</sup>lt;sup>14</sup>Claims 1, 2, 7, 9, 14, and 15 of the '652 Patent; claims 1, 3, 13, and 16 of the '255 Patent; and claims 1, 5, 7, 11, 17, 18 of the '143 Patent.

Dickinson's products do not infringe these claims. The Court agrees that Becton Dickinson's opposition is essentially a belated claim construction argument.<sup>15</sup> In short, Becton Dickinson argues that "is" means "is" and Gen-Probe argues that under Becton Dickinson's construction, "is" means "is and only is."

In construing claim terms, the Court must look "to the surrounding text of the claims in question, *the other claims*, the written description, and the prosecution history." *Brookhill-Wilk 1*, *LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1300 (Fed. Cir. 2003) (emphasis added). Additionally, a "construction that renders asserted claims facially nonsensical cannot be correct." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1255 (Fed. Cir. 2010).

Claim 13 of the '255 Patent depends on claim 10 of the '255 Patent and claim 14 of the '652 Patent depends on claim 11 of the '652 Patent. Claims 10 and 11 of the respective patents include the relevant language above and claims 13 and 14 respectively specifically include the use of two amplification techniques that require the amplification product to include an adjacent nucleic acid sequence that is not the target nucleic acid sequence — Strand Displacement Amplification (SDA) and Ligase Chain Reaction (LCR). This means that if the Court adopts Becton Dickinson's proposed construction, the claims would claim the use of an amplification technique that is impossible under the claim each depends on. Because this construction "renders the asserted claims facially nonsensical, [it] cannot be correct." *Id.* The Court rejects Becton Dickinson's newly proposed construction and will not deny summary judgment to Gen-Probe on this basis.

# b. Dr. Kricka's Testimony

Becton Dickinson argues that the Court should deny summary judgment on direct literal infringement based on Gen-Probe's expert report on invalidity.<sup>16</sup> Gen-Probe's expert, Dr. Kricka, in

<sup>&</sup>lt;sup>15</sup>Relying on *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, Gen-Probe requests that the Court conduct further claim construction proceedings before the matter is submitted to the jury if the Court accepts Becton Dickinson's belated claim construction argument. 521 F.3d 1351, 1362 (Fed. Cir. 2008) (finding interpretation of claim term "only if" improperly submitted to a jury and remanding for construction).

<sup>&</sup>lt;sup>16</sup>Becton Dickinson does not offer its own expert's opinion on infringement and never disclosed the argument it makes now as a possible infringement defense.

addressing invalidity, indicates that the Automation Patents are distinguishable from the prior art because the prior art taught physical separation between the pre-amplified sample and post-amplification steps. Becton Dickinson argues that this opinion raises a genuine issue of material fact because Becton Dickinson's products use a sealed tube approach known and practiced in the prior art and distinguishable from the Automation Patents.

This is essentially a creative way to assert practicing the prior art as a defense to literal infringement. "But 'practicing the prior art' is not a defense to literal infringement." *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002) (quoting *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995)). Becton Dickinson cannot claim it does not infringe because its products more closely resemble prior art than the asserted claims because this goes to validity, not infringement. *Id.* (precluding non-infringement defense that relied on showing product was more similar to prior art than asserted patent). Gen-Probe accurately notes that Becton Dickinson can argue to a jury that Dr. Kricka's report supports Becton Dickinson's invalidity defenses, but it is not a defense to infringement. The Court **GRANTS** partial summary judgment of direct literal infringement of the sixteen Automation Patent claims.

# 2. Inducement of Infringement and Contributory Infringement

Gen-Probe moves for summary judgment for inducement of infringement. Inducement "requires that the accused inducer act with knowledge that the induced acts constitute patent infringement." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, — F.3d —, 2012 WL 3764695, at \*3 (Fed. Cir. 2012) (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011)). The alleged infringer must "knowingly induce[] infringement and possess[] specific intent to encourage another's infringement." *Id.* The parties agree that contributory infringement requires the same specific intent as inducement. *Global-Techs.*, 131 S. Ct. at 2067-68.

Becton Dickinson obtained an opinion letter in November 2008. The legal opinion indicated that the claims of the '892 Patent, the only patent issued at the time, was invalid for obviousness. Becton Dickinson argues that this opinion letter and subsequent legal opinions obtained are sufficient to create a triable issue of fact on whether Becton Dickinson had the requisite specific intent to

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encourage another's infringement. Gen-Probe argues that an opinion on invalidity cannot defeat a scienter requirement that concerns infringement because infringement and invalidity are separate issues.

The parties acknowledge the Federal Circuit has not addressed this issue. The district courts that have addressed the issue have varied from excluding argument concerning an opinion letter on invalidity entirely as irrelevant to the infringement analysis to finding an opinion letter on invalidity sufficient to completely negate the requisite specific intent and granting summary judgment to a defendant on inducement. *See e.g., Applera Corp. v. MJ Research, Inc.*, No. 3:98CV1201, 2004 WL 367616, at \*1 (D. Conn. Feb. 24, 2004) ("Defendants may not argue . . . that opinions concerning invalidity. . . are relevant to the intent element" of inducement); *Bose Corp. v. SDI Tech. Imation Corp.*, No. 09-11439, 2012 WL 2862057, at \*11 (D. Mass. July 10, 2012) (finding plaintiff could not "prove the specific intent necessary to proceed to trial on contributory infringement or inducement" because it was undisputed that defendant had an invalidity opinion that defendant believed).

Rather than find that the opinion letter is entirely excluded from considerations of infringement or that it is dispositive in favor of Becton Dickinson, the Court finds the opinion letter is sufficient to create a triable issue of fact. *See VNUS Med. Techs., Inc. v. Diomed Holdings, Inc.*, No. C-05-2972, 2007 WL 2900532, at \*1 (N.D. Cal. Oct. 2, 2007) (finding triable issue of fact exists as to whether defendant was liable for inducing infringement based on opinion on infringement and invalidity). On summary judgment, drawing all inferences in Becton Dickinson's favor, the Court cannot say that no reasonable jury could return a verdict for Becton Dickinson. In *DSU Medical Corp. v. JMS Co.*, the court upheld a jury verdict that a defendant did not induce infringement because it lacked specific intent, based in part on opinion letters from counsel advising that a product did not infringe. 471 F.3d 1293, 1307 (Fed. Cir. 2006). While Becton Dickinson's opinion letter concerns invalidity rather than infringement, "invalid claims cannot give rise to liability for infringement." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1320 (Fed. Cir. 2009). Because there are genuine issues of material fact concerning whether Becton Dickinson had the requisite specific intent, Gen-Probe's motion for

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summary judgment is **DENIED** as to inducement of infringement and contributory infringement.<sup>17</sup>

### **CONCLUSION**

Becton Dickinson's Motion to Dismiss for Lack of Subject-Matter Jurisdiction is **DENIED**.

Becton Dickinson's Motion for Summary Judgment of Invalidity of the '308 Patent is **DENIED**.

Gen-Probe's Motion for Summary Judgment of Infringement of the '308 Patent is **GRANTED**.

Becton Dickinson's Motion for Summary Judgment of Invalidity of the Automation Patents is **DENIED**. Gen-Probe's Motion for Partial Summary Judgment of Infringement and No Invalidity of the Automation Patents is **GRANTED** in part and **DENIED** in part. Becton Dickinson's Motion for Summary Judgment of Non-Infringement is **GRANTED**.

The parties shall file a new proposed pretrial order consistent with the Court's summary judgment rulings on or before October 5, 2012.

The pending motion to file documents under seal, (Docket No. 443) is **DENIED** with leave to refile the motion on before **October 9, 2012** with explanation how the identified documents are subject to the protective order. However, the submitted documents will remain under seal until October 9, 2012.

### IT IS SO ORDERED.

DATED: September 28, 2012

Hon. Roger T. Benitez

United States District Judge

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<sup>&</sup>lt;sup>17</sup>Because the Court finds genuine issues of material fact preclude summary judgment for Gen-Probe on contributory infringement, the Court need not address Becton Dickinson's argument that its products are staple articles suitable for substantial non-infringing use.

<sup>&</sup>lt;sup>18</sup>Gen-Probe's Ex Parte Motion to Strike Factual Misstatements by Becton Dickinson's counsel is **DENIED** as moot. (Docket No. 381.)